

§ 1500.19 Misbranded toys and other articles intended for use by children.

(a) *Definitions.* For the purposes of this section, the following definitions shall apply.

(1) *Ball* means a spherical, ovoid, or ellipsoidal object that is designed or intended to be thrown, hit, kicked, rolled, dropped, or bounced. The term “ball” includes any spherical, ovoid, or ellipsoidal object that is attached to a toy or article by means of a string, elastic cord, or similar tether. The term “ball” also includes any multi-sided object formed by connecting planes into a generally, spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball, and any novelty item of a generally spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball. The term “ball” does not include dice, or balls permanently enclosed inside pinball machines, mazes, or similar outer containers. A ball is permanently enclosed if, when tested in accordance with 16 CFR 1500.53, it is not removed from the outer container.

(2) *Small ball* means a ball that, under the influence of its own weight, passes, in any orientation, entirely through a circular hole with a diameter of 1.75 inches (44.4 mm.) in a rigid template ¼ inches (6 mm.) thick. In testing to evaluate compliance with this regulation, the diameter of opening in the Commission’s test template shall be no greater than 1.75 inches (44.4 mm.).

(3) *Latex balloon* means a toy or decorative item consisting of a latex bag that is designed to be inflated by air or gas. The term does not include inflatable children’s toys that are used in aquatic activities such as rafts, water wings, swim rings, or other similar items.

(4) *Marble* means a ball made of a hard material, such as glass, agate, marble or plastic, that is used in various children’s games, generally as a playing piece or marker. The term “marble” does not include a marble permanently enclosed in a toy or game. A marble is permanently enclosed if, when tested in accordance with 16 CFR 1500.53, it is not removed from the toy or game.

(5) *Small part* means any object which, when tested in accordance with the procedures contained in 16 CFR 1501.4(a) and 1501.4(b)(1), fits entirely within the cylinder shown in Figure 1 appended to 16 CFR part 1501. The use and abuse testing provisions of 16 CFR 1500.51 through 1500.53 and 1501.4(b)(2) do not apply to this definition.

(6) *Package* or packaging refers to the immediate package in which a product subject to labeling under section 24 of the act is sold, as well as to any outer container or wrapping for that package.

(7) *Descriptive material* means any discrete piece of written material separate from the label of the package that contains an instruction (whether written or otherwise) for the use of a product subject to these labeling requirements, any depiction of the product, and any written material that specifically describes any function, use, warnings, user population, design or material specification, or other characteristic of the product. A catalog or other marketing material or advertisement that depicts other products in addition to the product it accompanies is not “descriptive material” unless it contains additional information, such as instructions for use of the product it accompanies or lists of accessories exclusively for use with that product, that are designed to focus the purchaser’s attention on the product. Descriptive material “accompanies” a product subject to the labeling requirements when it is packaged with the product or when it is intended to be distributed with the product at the time of sale or delivery to the purchaser. “Descriptive material” does not include statements that appear on the package of a product subject to the labeling requirements. “Descriptive material” does not include material intended solely for use by children if the package it accompanies contains a separate package insert prominently identified as a warning for parents that contains the required precautionary statements.

(8) *Bin and container for retail display* mean containers in which multiple unpackaged and unlabeled items are held for direct selection by and sale to consumers.

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(b) *Misbranded toys and children's articles.* Pursuant to sections 2(p) and 24 of the FHSA, the following articles are misbranded hazardous substances if their packaging, any descriptive material that accompanies them, and, if unpackaged and unlabeled, any bin in which they are held for sale, any container in which they are held for retail display, or any vending machine from which they are dispensed, fails to bear the labeling statements required in paragraphs (b) (1) through (4) and paragraph (f)(3) of this section, or if such labeling statements fail to comply with the prominence and conspicuous-

ness requirements of paragraph (d) of this section.

(1) With the exception of books and other articles made of paper, writing materials such as crayons, chalk, pencils, and pens, modeling clay and similar products, fingerpaints, watercolors, and other paint sets, and any other article identified in 16 CFR 1501.3 (other than balloons), any article that is a toy or game intended for use by children who are at least three years old but less than six years of age shall bear or contain the following cautionary statement if the toy or game includes a small part:



WARNING:

**CHOKING HAZARD--Small parts
Not for children under 3 yrs.**

(2) Any latex balloon, or toy or game that contains a latex balloon, shall bear the following cautionary statement:



WARNING:

**CHOKING HAZARD--Children under 8 yrs. can
choke or suffocate on uninflated or broken balloons.
Adult supervision required.**

**Keep uninflated balloons from children.
Discard broken balloons at once.**

(3)(i) Any small ball intended for children three years of age or older shall bear the following cautionary statement:



WARNING:

**CHOKING HAZARD--This toy is a small ball.
Not for children under 3 yrs.**

(ii) Any toy or game intended for children who are at least three years old but less than eight years of age that contains a small ball shall bear the following cautionary statement:



WARNING:

**CHOKING HAZARD--Toy contains a small ball.
Not for children under 3 yrs.**

(4)(i) Any marble intended for children three years of age or older shall bear the following cautionary statement:



WARNING:

**CHOKING HAZARD--This toy is a marble.
Not for children under 3 yrs.**

(ii) Any toy or game intended for children who are at least three years old but less than eight years of age that contains a marble shall bear the following cautionary statement:



WARNING:

**CHOKING HAZARD--Toy contains a marble.
Not for children under 3 yrs.**

(c) *Age of intended user.* In determining the ages of the children for which any toy or article subject to this section is intended, the following factors are relevant: the manufacturer's stated intent (such as the age stated on a label) if it is reasonable; the advertising, marketing, and promotion of the article; and whether the article is commonly recognized as being intended for children in this age group. In enforcing this provision, the Commission will follow the procedures set forth in 16 CFR 1501.5.

(d) *Prominence and conspicuousness of labeling statements.* The requirements of 16 CFR 1500.121 relating to the prominence and conspicuousness of precautionary labeling statements for hazardous substances shall apply to any labeling statement required under §1500.19(b) and (f), with the following clarifications and modifications.

(1) All labeling statements required by §1500.19(b) and (f) shall be in the

English language. The statements required by paragraph (b) need not appear in the format and layout depicted in paragraph (b). The statements required by 16 CFR 1500.19(b) and (f) shall be blocked together within a square or rectangular area, with or without a border. This means that the statements must appear on at least two lines. The statements shall be separated from all other graphic material by a space no smaller than the minimum allowable height of the type size for other cautionary material (e.g., the phrase "Not for children under 3 yrs.>"). If not separated by that distance, the labeling statements must be surrounded by a border line. Label design, the use of vignettes, or the proximity of other labeling or lettering shall not obscure or render inconspicuous any labeling statement required under §1500.19(b) and (f). This means that such statements shall appear on a solid background, which need not differ from

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the background color or any other color on the package label.

(2) The words "WARNING" or "SAFETY WARNING" required by section 24 of the FHSA shall be regarded as signal words.

(3) The statement "CHOKING HAZARD" shall be regarded as a statement of the principal hazard associated with the products subject to this section.

(4) All other remaining statements required by this section shall be regarded as "other cautionary material" as that term is defined in 16 CFR 1500.121(a)(2)(viii).

(5) The principal display panel for a bin, container for retail display, or vending machine shall be the side or surface designed to be most prominently displayed, shown, or presented to, or examined by, prospective purchasers. In the case of bins or containers for retail display, the cautionary material may be placed on a display card of a reasonable size in relationship to the surface area of the bin or container. The area of the display card shall constitute the area of the principal display panel. In the case of vending machines that contain a display card, the cautionary label may be placed either on the display card, on the coinage indicator decal, or on the glass or clear plastic of the machine. If there is no display card inside a vend-

ing machine, the size of the principal display panel will be calculated in accordance with 16 CFR 1500.121(c) based on the size of the front of the container from which items are dispensed, exclusive of the area of metal attachments, coin inserts, bases, etc. Any other side or surface of such a bin, container for retail sale, or vending machine that bears information, such as price or product description, for examination by purchasers shall be deemed to be a principal display panel, excluding any side or surface with information that only identifies the company that owns or operates a vending machine.

(6) All of the labeling statements required by this section, including those classified as "other cautionary material," must appear on the principal display panel of the product, except as provided for by §1500.19(f). Any signal word shall appear on the same line and in close proximity to the triangle required by section 24 of the act. Multiple messages should be provided with sufficient space between them, when feasible, to prevent them from visually blending together.

(7) All labeling statements required by this section shall comply with the following type size requirements. 16 CFR 1500.121(c)(1) explains how to compute the area of the principal display panel and letter height.

Area sq. in	0-2	+2-5	+5-10	+10-15	+15-30	+30-100	+100-400	+400
Type Size								
Sig. Wd	3/64"	1/16"	3/32"	7/64"	1/8"	5/32"	1/4"	1/2"
St. Haz	3/64"	3/64"	1/16"	3/32"	3/32"	7/64"	5/32"	1/4"
Oth. Mat	1/32"	3/64"	1/16"	1/16"	5/64"	3/32"	7/64"	5/32"

(8) Labeling required by this section that appears on a bin, container for retail display, or vending machine shall be in reasonable proximity to any pricing or product information contained on the principal display panel, or, if such information is not present, in close proximity to the article that is subject to the labeling requirements.

(9) Descriptive material that accompanies a product subject to the labeling requirements, including accompanying material subject to the alternative allowed by §1500.19(f), shall comply with the requirements of 16 CFR 1500.121(c)(6) relating to literature con-

taining instructions for use which accompanies a hazardous substance. If the descriptive material contains instructions for use, the required precautionary labeling shall be in reasonable proximity to such instructions or directions and shall be placed together within the same general area (see 16 CFR 1500.121(c)(6)).

(10) In the case of any alternative labeling statement permitted under §1500.19(e), the requirements of 16 CFR 1500.121(b)(3) and 1500.121(c)(2)(iii) shall apply to statements or indicators on the principal display panel directing attention to the complete cautionary

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labeling that appears on another display panel.

(11) Any triangle required by this section shall be an equilateral triangle. The height of such a triangle shall be equal to or exceed the height of the letters of the signal word “WARNING”. The height of the exclamation point inside the triangle shall be at least half the height of the triangle, and the exclamation point shall be centered vertically in the triangle. The triangle shall be separated from the signal word by a distance at least equal to the space occupied by the first letter of the signal word. In all other respects, triangles with exclamation points shall conform generally to the provisions of 16 CFR 1500.121 relating to signal words.

(e) *Combination of labeling statements.* The labels of products that contain more than one item subject to the requirements of this section may combine information relating to each of the respective hazards, if the resulting condensed statement contains all of the information necessary to describe

the hazard presented by each article. However, in the case of a product that contains a balloon and another item subject to the labeling requirements, only the signal word and statement of hazard may be combined.

(f) *Alternative labeling statements for small packages.* Any cautionary statement required by section 1500.19(b) may be displayed on a display panel of the package of a product subject to the labeling requirement other than the principal display panel only if:

(1) The package has a principal display panel of 15 square inches or less,

(2) The full labeling statement required by paragraph (b) of this section is displayed in three or more languages on another display panel of the package of the product, and

(3)(i) In the case of a toy or game subject to §1500.19(b)(1), a small ball subject to §1500.19(b)(3), a marble subject to §1500.19(b)(4), or a toy or game containing such a ball or marble, the principal display panel of the package bears the statement:



SAFETY WARNING

and bears an arrow or other indicator pointing toward or directing the purchaser's attention to the display panel on the package where the full labeling statement appears, or

(ii) In the case of a balloon subject to §1500.19(b)(2) or a toy or game containing such a balloon, the principal display panel bears the statement:



WARNING--CHOKING HAZARD

and bears an arrow or other indicator pointing toward or directing the purchaser's attention to the display panel on the package where the full labeling statement appears.

(g) *Alternative for products manufactured outside the United States.* In the case of a product subject to the labeling requirements of §1500.19(b) which is

manufactured outside the United States and is shipped directly from the manufacturer to the consumer by United States mail or other delivery service in an immediate package that contains descriptive material, the descriptive material inside the immediate package of the product need not bear the required labeling statement

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only if the shipping container of the product contains other accompanying material that bears the required statements displayed in a prominent and conspicuous manner. Products shipped from abroad to a U.S. affiliate for shipment to consumers are included within the scope of this exception.

(h) *Preemption.* Section 101(e) of the Child Safety Protection Act of 1994 prohibits any state or political subdivision of a state from enacting or enforcing any requirement relating to cautionary labeling addressing small parts hazards or choking hazards associated with any toy, game, marble, small ball, or balloon intended or suitable for use by children unless the state or local requirement is identical to a requirement established by section 24 of the FHSA or by 16 CFR 1500.19. Section 101(e) allows a state or political subdivision of a state to enforce a non-identical requirement relating to cautionary labeling warning of small parts hazards or choking hazards associated with any toy subject to the provisions of section 24 of FHSA until January 1, 1995, if the non-identical requirement was in effect on October 2, 1993.

[60 FR 10752, Feb. 27, 1995, as amended at 60 FR 41802, Aug. 14, 1995]

§ 1500.40 Method of testing toxic substances.

The method of testing the toxic substances referred to in § 1500.3(c) (1)(ii)(C) and (2)(iii) is as follows:

DIMENSIONS OF SLEEVES FOR ACUTE DERMAL TOXICITY TEST

[Test animal—Rabbits]

Measurements in centimeters		Range of weight of animals (grams)	Average area of exposure (square centimeters)	Average percentage of total body surface
Diameter at ends	Overall length			
7.0	12.5	2,500–3,500	240	10.7

(b) *Preparation of test animal.* The animals are prepared by clipping the skin of the trunk free of hair. Approximately one-half of the animals are then further prepared by making epidermal abrasions every 2 or 3 centimeters longitudinally over the area of exposure. The abrasions are sufficiently deep to penetrate the stratum corneum (horny layer of the epidermis) but not to

(a) *Acute dermal toxicity (single exposure).* In the acute exposures, the agent is held in contact with the skin by means of a sleeve for periods varying up to 24 hours. The sleeve, made of rubber dam or other impervious material, is so constructed that the ends are reinforced with additional strips and should fit snugly around the trunk of the animal. The ends of the sleeve are tucked, permitting the central portion to “balloon” and furnish a reservoir for the dose. The reservoir must have sufficient capacity to contain the dose without pressure. In the following table are given the dimensions of sleeves and the approximate body surface exposed to the test substance. The sleeves may vary in size to accommodate smaller or larger subjects. In the testing of unctuous materials that adhere readily to the skin, mesh wire screen may be employed instead of the sleeve. The screen is padded and raised approximately 2 centimeters from the exposed skin. In the case of dry powder preparations, the skin and substance are moistened with physiological saline prior to exposure. The sleeve or screen is then slipped over the gauze that holds the dose applied to the skin. In the case of finely divided powders, the measured dose is evenly distributed on cotton gauze which is then secured to the area of exposure.

distrub the derma; that is, not to obtain bleeding.

(c) *Procedures for testing.* The sleeve is slipped onto the animal which is then placed in a comfortable but immobilized position in a multiple animal holder. Selected doses of liquids and solutions are introduced under the sleeve. If there is slight leakage from the sleeve, which may occur during the